General

Guideline Title

Adult urodynamics: American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline.

Bibliographic Source(s)

Winters JC, Dmochowski RR, Goldman HB, Herndon CD, Kobashi KC, Kraus SR, Lemack GE, Nitti VW, Rovner ES, Wein AJ. Adult urodynamics: American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline. Linthicum (MD): American Urological Association (AUA); 2012 Apr. 30 p. [119 references]

Guideline Status

This is the current release of the guideline.

Recommendations

Major Recommendations

Definitions for the body of evidence strength (grade A, B, or C), the strength of the recommendations (standard, recommendation, option), and for statements labeled as Clinical Principle and Expert Opinion are provided at the end of the "Major Recommendations" field.

Stress Urinary Incontinence (SUI)/Prolapse

1. Clinicians who are making the diagnosis of urodynamic stress incontinence should assess urethral function. (*Recommendation; Evidence Strength: Grade C*)
2. Surgeons considering invasive therapy in patients with SUI should assess post-void residual (PVR) urine volume. (*Expert Opinion*)
3. Clinicians may perform multi-channel urodynamics in patients with both symptoms and physical findings of stress incontinence who are considering invasive, potentially morbid or irreversible treatments. (*Option; Evidence Strength: Grade C*)
4. Clinicians should perform repeat stress testing with the urethral catheter removed in patients suspected of having SUI who do not demonstrate this finding with the catheter in place during urodynamic testing. (*Recommendation; Evidence Strength: Grade C*)
5. Clinicians should perform stress testing with reduction of the prolapse in women with high grade pelvic organ prolapse (POP) but without the symptom of SUI. Multi-channel urodynamics with prolapse reduction may be used to assess for occult stress incontinence and detrusor dysfunction in these women with associated lower urinary tract symptoms (LUTS). (*Option; Evidence Strength: Grade C*)

Overactive Bladder (OAB), Urgency Urinary Incontinence (UUI), Mixed Incontinence

6. Clinicians may perform multi-channel filling cystometry when it is important to determine if altered compliance, detrusor overactivity (DO) or

other urodynamic abnormalities are present (or not) in patients with urgency incontinence in whom invasive, potentially morbid or irreversible treatments are considered. (*Option; Evidence Strength: Grade C*)

7. Clinicians may perform pressure flow studies (PFS) in patients with urgency incontinence after bladder outlet procedures to evaluate for bladder outlet obstruction. (*Expert Opinion*)
8. Clinicians should counsel patients with urgency incontinence and mixed incontinence that the absence of DO on a single urodynamic study does not exclude it as a causative agent for their symptoms. (*Clinical Principle*)

Neurogenic Bladder (NGB)

9. Clinicians should perform PVR assessment, either as part of a complete urodynamic study or separately, during the initial urological evaluation of patients with relevant neurological conditions (e.g., spinal cord injury and myelomeningocele) and as part of ongoing follow-up when appropriate. (*Standard; Evidence Strength: Grade B*)
10. Clinicians should perform a complex cystometrogram (CMG) during initial urological valuation of patients with relevant neurological conditions with or without symptoms and as part of ongoing follow-up when appropriate. In patients with other neurological diseases, physicians may consider CMG as an option in the urological evaluation of patients with LUTS. (*Recommendation; Evidence Strength: Grade C*)
11. Clinicians should perform pressure flow analysis during the initial urological valuation of patients with relevant neurological conditions with or without symptoms and as part of ongoing follow-up when appropriate, in patients with other neurologic disease and elevated PVR or in patients with persistent symptoms. (*Recommendation, Evidence Strength: Grade C*)
12. When available, clinicians may perform fluoroscopy at the time of urodynamics (videourodynamics) in patients with relevant neurologic disease at risk for neurogenic bladder, in patients with other neurologic disease and elevated PVR or in patients with urinary symptoms. (*Recommendation; Evidence Strength: Grade C*)
13. Clinicians should perform electromyography (EMG) in combination with CMG with or without PFS in patients with relevant neurologic disease at risk for neurogenic bladder, in patients with other neurologic disease and elevated PVR or in patients with urinary symptoms. (*Recommendation; Evidence Strength: Grade C*)

LUTS

14. Clinicians may perform PVR in patients with LUTS as a safety measure to rule out significant urinary retention both initially and during follow up. (*Clinical Principle*)
15. Uroflow may be used by clinicians in the initial and ongoing evaluation of male patients with LUTS when an abnormality of voiding/emptying is suggested. (*Recommendation; Evidence Strength: Grade C*)
16. Clinicians may perform multi-channel filling cystometry when it is important to determine if DO or other abnormalities of bladder filling/urine storage are present in patients with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (*Expert Opinion*)
17. Clinicians should perform PFS in men when it is important to determine if urodynamic obstruction is present in men with LUTS, particularly when invasive, potentially morbid or irreversible treatments are considered. (*Standard: Evidence Strength: Grade B*)
18. Clinicians may perform PFS in women when it is important to determine if obstruction is present. (*Option; Evidence Quality: Grade C*)
19. Clinicians may perform videourodynamics in properly selected patients to localize the level of obstruction, particularly for the diagnosis of primary bladder neck obstruction. (*Expert Opinion*)

Definitions:

Body of Evidence Strength

Grade A: Well-conducted randomized controlled trials (RCTs) or exceptionally strong observational studies

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data). Because treatment data for this condition are difficult to interpret in the absence of a placebo control, bodies of evidence comprised entirely of studies that lacked placebo control groups (i.e., observational studies) were assigned a strength rating of Grade C.

Rating Scheme for Strength of Recommendations

Standards are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade A or Grade B evidence.

Recommendations are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits)

be undertaken based on Grade C evidence.

Options are non-directive statements that leave the decision to take an action up to the individual clinician and patient because the balance between benefits and risks/burdens appears relatively equal or unclear; the decision is based on full consideration of the patient's prior clinical history, current quality of life, preferences and values. Options may be supported by Grade A, B, or C evidence.

A Clinical Principle is a statement about a component of clinical care that is widely agreed upon by urologists or other clinicians for which there may or may not be evidence in the medical literature.

Expert Opinion refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge and judgment for which there may be no evidence.

Clinical Algorithm(s)

None provided

Scope

Disease/Condition(s)

Lower urinary tract symptoms (LUTS) and conditions, including:

- Stress urinary incontinence
- Pelvic organ prolapse
- Overactive bladder
- Urgency urinary incontinence
- Mixed incontinence
- Neurogenic bladder

Guideline Category

Counseling

Diagnosis

Evaluation

Management

Clinical Specialty

Family Practice

Internal Medicine

Obstetrics and Gynecology

Urology

Intended Users

Advanced Practice Nurses

Physician Assistants

Physicians

Guideline Objective(s)

- To review the literature regarding the use of urodynamic testing in common lower urinary tract symptoms (LUTS) conditions
- To assist the clinician in the appropriate selection of urodynamic tests following an appropriate evaluation and symptom characterization

Target Population

Adults with lower urinary tract symptoms (LUTS)

Interventions and Practices Considered

1. Assessment of urethral function, with and without a catheter
2. Post-void residual urine volume
3. Multi-channel urodynamic stress testing with prolapse reduction in women with high-grade pelvic organ prolapse
4. Multi-channel filling cystometry
5. Pressure flow study (PFS)
6. Complex cystometrogram (CMG)
7. Fluoroscopy (videourodynamics)
8. Electromyography with CMG, with or without PFS
9. Uroflow in male patients
10. Counseling patients on the meaning of testing outcomes

Major Outcomes Considered

- Utility of urodynamic studies (UDS) in diagnosis
- Prognosis following UDS and suggested treatment
- Clinical management decisions based on UDS
- Patient outcomes following UDS and treatment based on UDS:
    - Adverse events
    - Quality of life

Methodology

Methods Used to Collect/Select the Evidence

Hand-searches of Published Literature (Secondary Sources)

Searches of Electronic Databases

Description of Methods Used to Collect/Select the Evidence

A systematic review was conducted to identify published articles relevant to the use of urodynamic studies (UDS) in patients with various urologic conditions, disorders and symptoms. Literature searches were performed on English-language publications using the MEDLINE® and EMBASE databases from January 1, 1990 to March 10, 2011 using the terms "urodynamics," "stress incontinence," "mixed incontinence," "urge incontinence," "lower urinary tract dysfunction," "LUTS," "LUTD" as well as key words related to pelvic organ prolapse, and various neurological diseases and key words capturing the various urodynamic tests known to be used in patients suspected or known to have these conditions. For certain questions, the searches only covered studies published between January 1, 2000 and March 10, 2011. The latter includes questions relating to utility of cystometry for stress/urgency incontinence/mixed incontinence, lower urinary tract symptoms (LUTS) or pelvic organ prolapse,

utility of electromyography (EMG) for LUTS or pelvic organ prolapse and utility of any combination of urodynamic tests for stress/urgency/mixed incontinence or pelvic organ prolapse. Studies published after March 10, 2011 were not included as part of the evidence base considered by the Panel from which evidence-based guideline statements (Standards, Recommendations, Options) were derived.

Preclinical studies (e.g., animal models), pediatric studies, meeting abstracts, commentary, editorials, non-English language studies and studies of adults with urological conditions and symptoms other than those noted above were excluded. Studies with less than 10 patients were excluded from further evaluation and thus data extraction given the unreliability of the statistical estimates and conclusions that could be derived from them. Studies that did not report data separately for males and females for certain patient populations (e.g., incontinence, pelvic organ prolapse and LUTS) were excluded. Review article references were checked to ensure inclusion of all possibly relevant studies. Multiple reports on the same patient group were carefully examined to ensure inclusion of only non-redundant information.

Number of Source Documents

A total of 393 studies met the inclusion criteria and addressed some combination of urodynamic tests.

Methods Used to Assess the Quality and Strength of the Evidence

Weighting According to a Rating Scheme (Scheme Given)

Rating Scheme for the Strength of the Evidence

Body of Evidence Strength

Grade A: Well-conducted randomized controlled trials (RCTs) or exceptionally strong observational studies

Grade B: RCTs with some weaknesses of procedure or generalizability or generally strong observational studies

Grade C: Observational studies that are inconsistent, have small sample sizes, or have other problems that potentially confound interpretation of data). Because treatment data for this condition are difficult to interpret in the absence of a placebo control, bodies of evidence comprised entirely of studies that lacked placebo control groups (i.e., observational studies) were assigned a strength rating of Grade C.

Methods Used to Analyze the Evidence

Systematic Review with Evidence Tables

Description of the Methods Used to Analyze the Evidence

Urodynamic Tests, Conditions and Outcomes Reviewed During this Process

This systematic review evaluated the following urodynamic tests: post-void residual, uroflowmetry, cystometry, pressure-flow studies, videourodynamics, electromyography (EMG), urethral function tests (e.g., Valsalva leak point pressure [VLPP], urethral pressure profile) or any combination of the above. The target populations comprised adults with stress incontinence, mixed incontinence, urgency incontinence, lower urinary tract symptoms (LUTS), pelvic organ prolapse or neurogenic bladder. Outcomes of interest were grouped into four categories: diagnosis, prognosis, clinical management decisions or patient outcomes. Any outcome measure that could be classified in one of these categories was considered acceptable for review. A total of 393 studies met the inclusion criteria and addressed some combination of urodynamic tests, target populations and diagnostic categories noted above. Relevant data from these studies were extracted and summarized in evidence tables which comprise part of the full evidence report (available upon request).

Limitations of the Literature

The Panel proceeded with full awareness of the limitations of the urodynamics literature. These limitations include: poorly defined or heterogeneous patient groups, small sample sizes, lack of studies with diagnostically accurate data, lack of controlled studies with patient outcome data and the use of a variety of outcome measures. Overall, these difficulties precluded use of meta-analytic procedures or other quantitative analyses. Instead, narrative syntheses were used to summarize the evidence for the questions of interest.

Quality of Studies and Determination of Evidence Strength

Quality of individual studies was rated as high, moderate or low based on instruments tailored to specific study designs. Randomized controlled trials (RCTs) were assessed using the Cochrane Risk of Bias tool. Conventional diagnostic cohort studies, diagnostic case-control studies or diagnostic case series that presented data on diagnostic test characteristics were evaluated using the QUADAS tool that evaluates the quality of diagnostic accuracy studies. Cohort studies with a comparison of interest were evaluated with the Drug Effectiveness Review Project instrument. As there is no widely agreed upon quality assessment tool for case series that do not present data on diagnostic test characteristics, the quality of individual case series was not formally assessed with an instrument. Instead, these studies were labeled as low quality due to their study design.

The categorization of evidence strength is conceptually distinct from the quality of individual studies. Evidence strength refers to the body of evidence available for a particular question and includes consideration of study design, individual study quality, consistency of findings across studies, adequacy of sample sizes and the generalizability of samples, settings and treatments for the purposes of the guideline.

As most of the available evidence consisted of low quality case series, the majority of evidence was considered Grade C (see the "Rating Scheme for the Strength of the Evidence" field).

Methods Used to Formulate the Recommendations

Expert Consensus

Expert Consensus (Delphi)

Description of Methods Used to Formulate the Recommendations

This document was written by the Urodynamics Guidelines Panel of the American Urological Association (AUA) Education and Research, Inc., which was created in 2009. The Practice Guidelines Committee (PGC) of the AUA selected the panel chair. Panel members were selected by the chair. Membership of the panel included urologists, nurses, and other clinicians with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the use of urodynamics.

Linking Statement Type to Evidence Strength

The AUA nomenclature system explicitly links statement type to body of evidence strength and the Panel's judgment regarding the balance between benefits and risks/burdens.

To formulate evidence-based statements, the Panel used BRIDGE-Wiz (Building Recommendations In a Developer's Guideline Editor), a software application that employs natural language to create and populate a template for guideline statements. It limits verb choices, promotes active voice and incorporates decidability and executability checks to ensure creation of statements that are actionable by end users.

In some instances, the review revealed insufficient publications to address certain questions from an evidence basis; therefore, some statements are provided as Clinical Principles or as Expert Opinion with consensus achieved using a modified Delphi technique if differences of opinion emerged.

Rating Scheme for the Strength of the Recommendations

Rating Scheme for Strength of Recommendations

Standards are directive statements that an action should (benefits outweigh risks/burdens) or should not (risks/burdens outweigh benefits) be undertaken based on Grade A or Grade B evidence.

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may or may not be evidence in the medical literature.

Expert Opinion refers to a statement, achieved by consensus of the Panel, that is based on members' clinical training, experience, knowledge and judgment for which there may be no evidence.

Cost Analysis

A formal cost analysis was not performed and published cost analyses were not reviewed.

Method of Guideline Validation

Peer Review

Description of Method of Guideline Validation

This document was submitted for peer review to 84 urologists and other healthcare professionals, and 39 provided input. After the final revisions were made, based upon the peer review process, the document was submitted to and approved by the Practice Guidelines Committee (PGC) and the Board of Directors of the American Urological Association (AUA). Peer review comments are available upon request.

Evidence Supporting the Recommendations

Type of Evidence Supporting the Recommendations

The type of supporting evidence is identified and graded for selected recommendations (see the "Major Recommendations" field). Where evidence was lacking, recommendations are supported by expert opinion or consensus.

Benefits/Harms of Implementing the Guideline Recommendations

Potential Benefits

Improved patient outcomes through appropriate use of urodynamic tests for lower urinary tract symptoms (LUTS) conditions

Potential Harms

- Many types of urodynamic testing require urethral catheterization and include cystometry, pressure flow studies (PFS) and videourodynamic studies (VUDS) including urethral function testing. Such testing subjects patients to risks of urethral instrumentation including infection, urethral trauma and pain. The benefits of VUDS must be weighed against the potential risks, especially in patients with neurogenic bladder. The risks of infection, bleeding, discomfort and especially autonomic dysreflexia (AD) have been previously mentioned. Although the radiation dosage of videourodynamic studies is low, radiation exposure is additive. These studies should be done in a manner which provides the desired clinical information at the lowest possible radiation dose to the patient.
- Ultrasound is less invasive and painful than catheterization and does not introduce the risk of infection or urethral trauma. However, portable office ultrasound bladder scanners have a measure of operator independence and can be inaccurate in several clinical circumstances including obesity, prior lower abdominal surgery, cystic pelvic pathology, pregnancy, peritoneal dialysis and in the setting of ascites.
- During stress testing, the investigator should be aware that the instrument utilized for pelvic organ prolapse (POP) reduction may also obstruct the urethra creating a falsely elevated Valsalva leak point pressure (VLPP) or prevent the demonstration of SUI.
- The risks/harms of assessing post-void residual (PVR) using catheterization are low and include UTI or urethral trauma. These risks can be eliminated with ultrasound determination of PVR. However, measurement of PVR may be associated with false positives and negatives and thus could lead to inappropriate treatment. Therefore, it is recommended that decisions not be based on a single measurement.

Qualifying Statements

Qualifying Statements

- While these guidelines do not necessarily establish the standard of care, the American Urological Association (AUA) seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today, these evidence based guideline statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.
- Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ("off label") that are not approved by the Food and Drug Administration (FDA), or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines are not intended to provide legal advice about use and misuse of these substances.
- Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices. For this reason, the AUA does not regard technologies or management which are too new to be addressed by these guidelines as necessarily experimental or investigational.

Implementation of the Guideline

Description of Implementation Strategy

An implementation strategy was not provided.

Institute of Medicine (IOM) National Healthcare Quality Report Categories

IOM Care Need

Getting Better

Living with Illness

IOM Domain

Effectiveness

Patient-centeredness

Identifying Information and Availability

Bibliographic Source(s)

Winters JC, Dmochowski RR, Goldman HB, Herndon CD, Kobashi KC, Kraus SR, Lemack GE, Nitti VW, Rovner ES, Wein AJ. Adult

urodynamics: American Urological Association (AUA)/Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU) guideline. Linthicum (MD): American Urological Association (AUA); 2012 Apr. 30 p. [119 references]

Adaptation

Not applicable: The guideline was not adapted from another source.

Date Released

2012 Apr

Guideline Developer(s)

American Urological Association Education and Research, Inc. - Medical Specialty Society

Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction - Professional Association

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Funding of the committee was provided by the American Urological Association (AUA) and the Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction (SUFU). Committee members received no remuneration for their work.

Guideline Committee

Urodynamics Guidelines Panel

Composition of Group That Authored the Guideline

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Financial Disclosures/Conflicts of Interest

Conflict of Interest (COI) Disclosures

All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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Guideline Status

This is the current release of the guideline.

Guideline Availability

Electronic copies: Available from the American Urological Association, Inc. (AUA) Web site .

Availability of Companion Documents

None available

Patient Resources

None available

NGC Status

This NGC summary was completed by ECRI Institute on June 4, 2012. The information was verified by the guideline developer on June 11, 2012.

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